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Europäisches Patentamt

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(11)

Publication number:

**0 215 726  
A2**

(12)

**EUROPEAN PATENT APPLICATION**

(21) Application number: 86630131.0

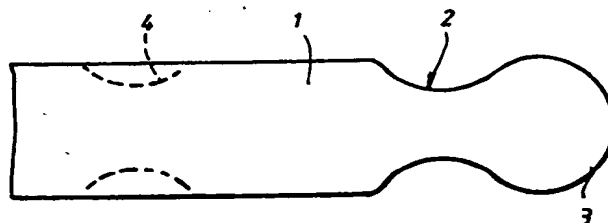
(51) Int. Cl.\*: **A 61 N 1/40, A 61 F 2/00**

(22) Date of filing: 19.08.86

(30) Priority: 19.08.85 AU 2025/85

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Bulletin 87/13(72) Inventor: **Clark, Graeme M.**, 13 Bannon Road, Eltham Victoria 3095 (AU)  
Inventor: **Franz, Burkhard Karl-Helz Gunther**, 24 Karwitha Street, Vermont Victoria 3133 (AU)(24) Designated Contracting States: **DE FR GB**(74) Representative: **Schmitz, Jean-Marie et al**, OFFICE DENNEMEYER S.à.r.l. P.O. Box 1502, L-1015 Luxembourg (LU)(54) **Prosthetic electrode array.**

(57) The invention provides an electrode suitable for biological implantation comprising support means and at least one electrode mounted on the support means which support means includes one or more discontinuities in the structure, shape or material of the support means positioned near one end of the support means to facilitate deflection of that end of said support means on encountering an obstacle during the implantation procedure. The invention provides an electrode array for prosthetic implantation, comprising a biologically inert support member having an inner end and an outer end, a plurality of electrodes supported by said support member at predetermined space distances along a portion of the length of said support member.

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## 2 FIELD OF THE INVENTION

3 This invention relates to electrode arrays for use with  
4 prostheses such as a hearing prosthesis in which th  
5 electrode array is implanted in the cochlea of the patient.

## 6 BACKGROUND OF THE INVENTION

7 In Australian Patent 529974 (AU-B46563/79) there is  
8 described an electrode array suitable for implantation in  
9 the human cochlea to enable stimulation of the auditory  
10 nerves by electrical currents applied to the electrodes in  
11 the array. The electrode array described in the above  
12 patent has been the subject of commercial development by  
13 Nucleus Limited of 1 Woodcock Place, Lane Cove, New South  
14 Wales and is currently available as part of a hearing  
15 prosthesis package being marketed by Nucleus Limited.

16 Similar electrode arrays are also used in other  
17 prosthetic applications, for example, see United States  
18 patents 3752939 Bartz, 3995623 Blake et al and 4073283  
19 Bradley et al.

20 It has been determined that electrodes of the type  
21 presently used for implantation in the human cochlea may  
22 cause damage to structures within the cochlea, see for  
23 example, "Multichannel Intracochlear Elctrodes: Mechanism of  
24 Insertion Trauma" by David W. Kennedy M.D. (Proceedings of  
25 the Triologic Meeting in Otolaryngology Palm Beach Florida  
26 May 1986). This can occur because the tip of the electrode  
27 punctures or abrades the structures, or the shaft buckles  
28 and causes a tear of soft tissues or fracture of the bony  
29 tissues. We have observed in human temporal bones that the

1 electrode tip may cause damage to tissues because the outer  
2 wall of the inner ear is slightly splayed outwards. This  
3 causes the tip to be directed upwards towards the important  
4 soft tissues lying across the middle of the cochlear turn.  
5 Similar problems can occur with moulded electrode arrays of  
6 the type shown in United States patent 3752939.

7 BRIEF SUMMARY OF THE INVENTION

8 It is the object of the present invention to provide an  
9 improved electrode suitable for cochlear implantation, but  
10 not restricted thereto, in which the above problem is at  
11 least substantially ameliorated.

12 In its broadest form, the invention provides an  
13 electrode suitable for biological implantation comprising  
14 support means and at least one electrode mounted on the  
15 support means, characterized in that said support means  
16 includes one or more discontinuities in the structure, shape  
17 or material of the support means positioned near one end of  
18 the support means to facilitate deflection of that end of  
19 said support means on encountering an obstacle during the  
20 implantation procedure.

21 More particularly, the invention provides an electrode  
22 array for prosthetic implantation, comprising a biologically  
23 inert support member having an inner end and an outer end, a  
24 plurality of electrodes supported by said support member at  
25 predetermined space distances along a portion of the length  
26 of said support member, conducting wires associated with  
27 each electrode and passing through the outer end of said  
28 support member, and at least one discontinuity in the  
29 structure, shape or material of said support member, said

1 discontinuity being positioned such that the inner end of  
2 said support member may be deflected on encountering an  
3 obstacle during the implantation procedure.

4 In the case of an electrode suitable for cochlear  
5 implantation, the discontinuity is preferably positioned  
6 within the front one third of the length of the support  
7 member. In the case of an electrode array of the order of  
8 25 mm long, the discontinuity is located in a portion of the  
9 inner end of the support member which is about eight to ten  
10 mm long. In a particularly preferred form, a first  
11 discontinuity is located from 0.5 to 2 mm from the inner end  
12 of the support member. The discontinuity may take the form  
13 of a narrowing or neck formed in the support material, an  
14 element of more flexible material forming part of the  
15 support member, for example interposed between the inner end  
16 and the body of the support member, or forming the free end  
17 of the support member, or a combination of both. More than  
18 one discontinuity may be provided.

19 Studies on the movement of prototype electrode arrays  
20 embodying the above invention in human temporal bones have  
21 shown that the invention reduces the chance of damage to  
22 important structures because the inner end of the support  
23 member is directed downwardly away from these structures as  
24 the electrode array passes around the cochlear turn. The  
25 downward movement would seem due to the fact that the  
26 section in front of the discontinuity meets frictional  
27 forces on the outer wall before the back section.  
28 Alternatively the creation of a discontinuity enables  
29 surgical manoeuvres to be carried out more effectively, for

1 example, rotation of the electrode, to similarly direct the  
2 tip away from important structures and to enable it to pass  
3 more easily around the cochlear turn.

4 A comparison of an electrode embodying the invention  
5 with a conventional electrode was conducted using a  
6 skeletonised human cochlea which allowed direct observation  
7 of the inserted electrodes passing the cochlea turns. While  
8 the electrode designed according to the invention allowed  
9 the array to pass through the cochlea turns without causing  
10 any damage to the structures of the cochlea and while  
11 passing through the cochlea turns staying well below the  
12 partition above, the conventional electrode penetrated the  
13 partition of the cochlea and caused a tear in the spiral  
14 ligament and the basilar membrane.

#### 15 BRIEF DESCRIPTION OF THE DRAWINGS

16 Several preferred embodiments in the invention will now  
17 be described with reference to the accompanying drawings in  
18 which:

19 Figure 1 is a schematic elevation of the inner end of a  
20 support member for an electrode array embodying the  
21 invention;

22 Figure 2 is a schematic elevation of the inner end of  
23 a support member according to an alternative embodiment of  
24 the invention; and

#### 25 DESCRIPTION OF PREFERRED EMBODIMENTS

26 Figure 3 is a schematic elevation of the inner end of a  
27 still further embodiment of the invention.

28 Referring firstly to Figure 1 of the drawings, a  
29 support member 1 for an array of electrodes (not shown) is

1 formed with a narrowing or neck 2 from 0.025 to 0.1 mm deep,  
2 0.1 to 0.5 mm wide and located from 0.5 to 2 mm from the  
3 inner ends 3 of the support member 1. The support member is  
4 preferably made from Silastic 4-4210 and the diameter of the  
5 inner end 3 is approximately 0.4 mm. Although not shown in  
6 the drawings, the support member 1 is tapered and is  
7 approximately 0.6 mm in diameter at its outer end. The  
8 support member is approximately 25 mm long and supports  
9 twenty electrodes in the form of conductive bands arranged  
10 in the manner described in our Australian patent number  
11 529974. However, the invention is equally applicable to  
12 electrode arrays having other suitable electrode structures.

13 If desired, a second discontinuity 4 may be provided  
14 and it is preferred that both discontinuities should be  
15 located within the inner most one third of the length of the  
16 support member 1, that is, approximately 8 to 10 mm from the  
17 inner end 3 of the support member 1. The above described  
18 arrangement makes it possible for the electrode array to  
19 pass around the cochlear turn without damage to the  
20 sensitive structures.

21 Although Silastic 4-4210 has been specified above,  
22 Silastic A or medical grade Silastic may be used as the  
23 material of the support member 1.

24 Referring now to Figure 2 of the drawings, a similar  
25 result may be achieved by interposing a short element 5 of  
26 biologically inert material having a different mechanical  
27 property between the body of the support member 1 and the  
28 inner end 3. In the embodiment shown, the body of the  
29 support member 1 and the inner end 3 are both made from

1 Silastic 4-4210 while the discontinuity 5 is made from  
2 Silastic A. The width of the discontinuity 5 is from 0.1 to  
3 0.5 mm, as in the preceding embodiment. A biocompatible  
4 glue may be used to secure the discontinuity 5 in position  
5 although it will be appreciated that the two types of  
6 Silastic bond readily when mixed for extrusion.

7 In an alternative embodiment not shown in the drawings,  
8 the inner end of the support member is made from Silastic A  
9 or the like. The end portion extending from the second  
10 broken line defining discontinuity 5 may be made entirely  
11 from Silastic A to achieve improved results.

12 In the embodiment of Figure 3, the embodiments of  
13 Figures 1 and 2 are effectively combined. Thus, a short  
14 section of Silastic A 6 having a necked form as shown in  
15 Figure 1 of the drawings is glued between the body of the  
16 support member 1 and its inner end 3. Again the dimensions  
17 are similar to those of the discontinuity shown in Figure 1  
18 of the drawings.

19 It will be appreciated that a number of discontinuities  
20 of any one or a combination of the above types may be  
21 provided along the length of the support member 1. Although  
22 the preferred embodiments described above are applicable to  
23 so-called free-fitting electrode arrays, the invention is  
24 equally applicable to moulded electrode arrays of the type  
25 described in United States patent 3752939. Similarly,  
26 although the dimensions and materials stipulated above are  
27 presently preferred, it will be appreciated that the  
28 positioning of a discontinuity at any suitable position near  
29 the inner end of the electrode array will improve the

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- 1 implantability of the electrode array and serve to
- 2 ameliorate the problem described above.



## 1 CLAIMS:

- 2 1. An electrode suitable for electrode suitable for  
3 biological implantation comprising support means and at  
4 least one electrode mounted on the support means,  
5 characterized in that said support means includes one or  
6 more discontinuities in the structure, shape or material of  
7 the support means positioned near one end of the support  
8 means to facilitate deflection of that end of said support  
9 means on encountering an obstacle during the implantation  
10 procedure.
- 11 2. An electrode array for prosthetic implantation,  
12 comprising a biologically inert support member having an  
13 inner end and an outer end, a plurality of electrodes  
14 supported by said support member at predetermined space  
15 distances along a portion of the length of said support  
16 member, conducting wires associated with each electrode and  
17 passing through the outer end of said support member, and at  
18 least one discontinuity in the structure, shape or material  
19 of said support member, said discontinuity being positioned  
20 such that the inner end of said support member may be  
21 deflected on encountering an obstacle during the  
22 implantation procedure.
- 23 3. The electrode array of claim 2, wherein said  
24 discontinuity is positioned within the first one third of  
25 the length of said support member.
- 26 4. The electrode array of claim 3, wherein said support  
27 member is about 25mm long, said discontinuity in a portion  
28 of the inner end of the support member which is about eight  
29 to ten mm long.

1 5. The array of claim 1, 2 or 3, wherein said  
2 discontinuity comprises a neck formed in the surface of said  
3 support member.

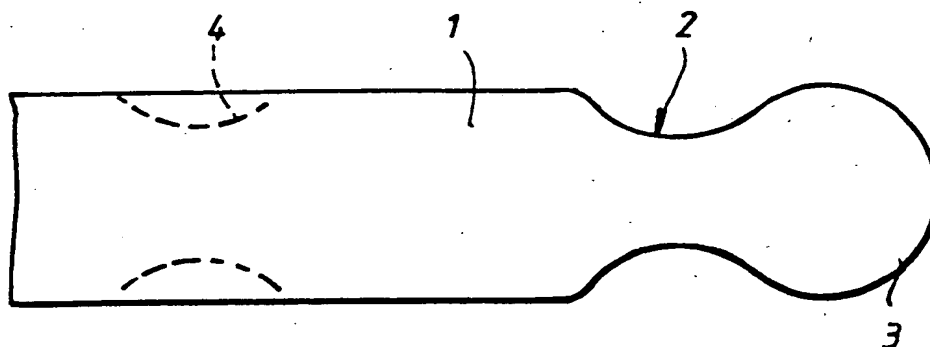
4 6. The array of claim 1, 2 or 2, wherein said  
5 discontinuity comprises an element of material more  
6 flexible than the material of said support member.

7 7. The electrode array of claim 4, wherein said  
8 discontinuity is located from 0.5 to 2mm from the inner end  
9 of the support member and comprises a neck in said support  
10 member from 0.1 to 0.15mm wide and 0.025 to 0.1mm deep.

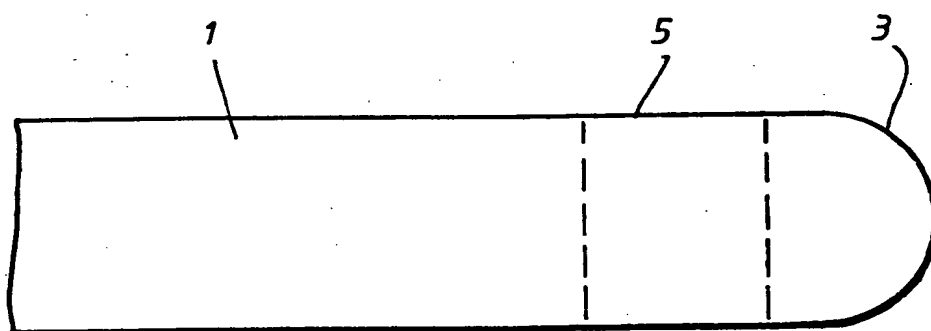
11 8. The electrode array of claim 4, wherein said  
12 discontinuity comprises a neck formed in the surface of said  
13 member and comprises an element of material more flexible  
14 than the material of the support member approximately 0.1 to  
15 0.5mm wide.

16 9. The electrode array of claim 6, wherein said element is  
17 nicked to a depth of 0.002 to 0.1mm.

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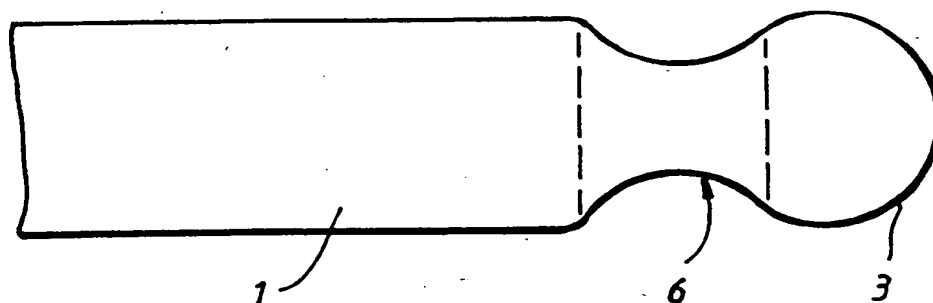


**FIG. 1.**



**FIG. 2.**

**FIG. 3.**



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**EUROPEAN PATENT APPLICATION**

21 Application number: 86630131.0

51 Int. Cl.<sup>3</sup>: **A 61 N 1/40**  
**A 61 F 2/00**

22 Date of filing: 19.08.86

30 Priority: 19.08.85 AU 2025/85

43 Date of publication of application:  
25.03.87 Bulletin 87/13

88 Date of deferred publication of search report: 19.04.89

84 Designated Contracting States:  
DE FR GB

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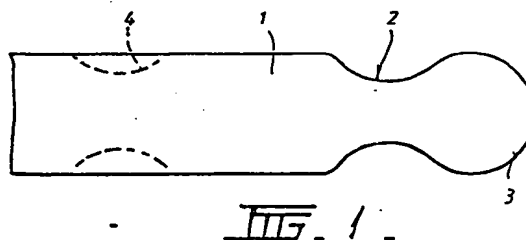
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64 **Prosthetic electrode array.**

57 The invention provides an electrode suitable for biological implantation comprising support means (1) and at least one electrode mounted on the support means (1) which support means includes one or more discontinuities (2) in the structure, shape or material of the support means positioned near one end (3) of the support means (1) to facilitate deflection of that end of said support means on encountering an obstacle during the implantation procedure. The invention provides an electrode array for prosthetic implantation, comprising a biologically inert support member (1) having an inner end (3) and an outer end, a plurality of electrodes supported by said support member at predetermined space distances along a portion of the length of said support member.



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# EUROPEAN SEARCH REPORT

Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 86630131.0
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
X	DE - A1 - 3 017 284 (BISPING) * Claims 1-3,10,16,17; fig. 1-4 *	1-3,5, 6,8	A 61 N 1/04 A 61 F 11/04 A 61 N 1/40 A 61 F 2/00
X	DE - A1 - 3 300 050 (SIEMENS) * Abstract; page 4, line 15 - page 5, line 1; fig. 1-3 *	1-3,6, 8	
A	EP - A2 - 0 099 253 (SHIONOGI) * Abstract; fig. 1 *	1-3,5	
A	EP - A2 - 0 084 972 (AXONICS) * Abstract; fig. 1 *	1,2	
A	DE - A1 - 2 502 620 (GARBE) * Fig. 1 *	1,2,5	TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
A	US - A - 3 749 100 (VON DER MOSEL) * Fig. 1,2 *	1,2,5	A 61 N A 61 B A 61 F H 04 R
A	WO - A1 - 80/02 231 (DONACHI) * Fig. 1,3 *	1,2,5, 6,8	
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 09-02-1989	Examiner NEGWER
<p><b>CATEGORY OF CITED DOCUMENTS</b></p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons &amp; : member of the same patent family, corresponding document</p>			

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# EUROPEAN SEARCH REPORT

Application number

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EP 86630131.0

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
A	SOVIET INVENTIONS ILLUSTRATED, P,Q sections, week C 41, November 19, 1980 DERWENT PUBLICATIONS LTD., London, P 31 * SU-718 086 (BAKAI) -----	1, 2, 5, 6, 8	
			TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 09-02-1989	Examiner NEGWER
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure D : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			